DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 18, 2015

HEBEI HONGSEN PLASTICS TECHNOLOGY CO., LTD
C/O Mr. Ray Wang
Beijing Believe Tech. Service Co., LTD
1-202, Build 3, Beijing New World, No. 5 Chaoyang Rd.
Chaoyang District, Beijing, 100024
China

Re: K150340
Trade/Device Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: NITRILE Patient Examination Gloves (Power Free)
Regulatory Class: I
Product Code: LZA
Dated: May 14, 2015
Received: May 18, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K150340

Device Name
POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)

Indications for Use (Describe)

The POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Exhibit #2 510(k) Summary

The assigned 510(k) Number: k150340

1. Date of Preparation: 2015/1/27

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)
Device Name: NITRILE Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Classification: I
Product Code: LZA
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for Use:
The POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: k131440
Product Name: Powder free Patient Examination Gloves, Blue Color
Manufacturer: Hebei HongSen Plastics Technology Co., Ltd.

6. Device Description

The proposed device, POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

Powder Free Nitrile Patient Examination Gloves are made of Nitrile rubber; available in four different colors (White, Cobalt Blue, Black, and Ice Blue) and five different sizes (XS-XL). The subject device is provided non-sterile and is a barrier.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.
ASTM D 5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent Comparison Conclusion

Table III-1 General Comparison

ITEM	Proposed Device (k150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Product Code	LZA	LZA	SE
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SE
Class	I	I	SE
Indication for use	The POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Titan powder free nitrile patient examination glove, blue color, is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. It has blue color and is sold as non-sterile.	SE
Powdered or Powder free	Powder free	Powder free	SE
Design Feature	ambidextrous, smooth	ambidextrous, smooth	SE
Labeling Information	Single-use indication, powder free, device name, glove size and quantity, Nitrile Examination Gloves, Non-Sterile	Single-use indication, powder free, device name, glove size and quantity, Nitrile Examination Gloves, Non-Sterile	SE

Table III -2 Device Dimensions Comparison

Proposed Device (k150340) POWDER FREE Nitrile GLOVES (White)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	300	300	300	300	300	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.12					±0.03
	Palm	0.10					±0.03
	Cuff	0.09					±0.03
Proposed Device (k150340) POWDER FREE Nitrile GLOVES (Cobalt Blue, Black)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.12					±0.03
	Palm	0.10					±0.03
	Cuff	0.09					±0.03
Proposed Device (k150340) POWDER FREE Nitrile GLOVES (Ice Blue)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.10					±0.03
	Palm	0.08					±0.03
	Cuff	0.06					±0.03
Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.12					±0.03
	Palm	0.10					±0.03
	Cuff	0.09					±0.03
Remark	Analysis 1						

Analysis 1:
The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D 6319.

Table III -3 Performance Comparison

ITEM			Proposed Device (k150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Colorant			White, Cobalt Blue, Black, Ice Blue	Blue	Analysis 3
Physical Properties	Before Aging	Tensile Strength	15 MPa, min for White; 15 MPa, min for Cobalt Blue; 15 MPa, min for Black; 15 MPa, min for Ice Blue;	15 MPa, min	SE
		Ultimate Elongation	500 % min for White; 500 % min for Cobalt Blue; 500 % min for Black; 500 % min for Ice Blue;	500 % min	SE
	After Aging	Tensile Strength	14 MPa, min for White; 14 MPa, min for Cobalt Blue; 14 MPa, min for Black; 14 MPa, min for Ice Blue;	14 MPa, min	SE
		Ultimate Elongation	500 % min for White; 400 % min for Cobalt Blue; 400 % min for Black; 400 % min for fro Ice Blue;	400 % min	Analysis 2
	Comply with ASTM D6319			Comply with ASTM D6319	SE
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	SE
Powder Content			Max. 0.7 mg per glove	Meet the requirements of ASTM 6319	SE

Analysis 2:
The proposed device has different Ultimate Elongation after aging specification to the predicate device, but all proposed device meets the specification requirements of ASTM D 6319.

Table III-4Safety Comparison

ITEM		Proposed Device (k150340) POWDER FREE Nitrile GLOVES (White, Cobalt Blue, Black, Ice Blue)	Predicate Device (k131440) Powder free Patient Examination Gloves, Blue Color	Remark
Material		Nitrile	Nitrile	SE
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
	Sensitization	Under conditions of the study, not a sensitizer.		
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	SE

Analysis 3:

The proposed device has different color to the predicate device, this different may causes potential biocompatibility risk, for this risk we conducted the biocompatibility test according to the ISO 10993-10, the test results showed that the proposed devices (White, Cobalt Blue, Black, Ice Blue) did not induce skin irritation and showed no significant evidence of causing skin sensitization.

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.